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Barry H. Jacobsen
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2000 Galloping Hill Rd.
Kenilworth, NJ 07033

In Re: Patent Term Extension
Application for
U.S. Patent No. 6,068,832

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NOTICE OF DETERMINATION ON ELIGIBILITY

An application for extension of the patent term of U.S. Patent No. 6,068,832 (the '832 patent) under 35 U.S.C. § 156 was filed in the United States Patent and Trademark Office on August 19, 2010. The application was filed by Schering Corporation. Extension is sought based upon the premarket review under § 505 of the Federal Food Drug and Cosmetic Act (FFDCA) of a human drug product known by the tradename DULERA® having the active ingredients mometasone furoate and formoterol fumarate. DULERA® was approved for commercial use and sale by the Food and Drug Administration (FDA) on June 22, 2010.

In a letter dated April 27, 2011 from FDA to the USPTO (FDA letter), the FDA indicated that DULERA® had been subject to a regulatory review period under NDA 22-518 in accordance with section 505 of the FFDCA and confirmed that the approval of DULERA® did not represent the first permitted commercial marketing or use of each of the active ingredients, mometasone furoate and formoterol fumarate.

A single request for reconsideration of this FINAL DETERMINATION OF INELIGIBILITY may be made if filed by the applicant within TWO MONTHS of the mailing date of this letter. The period for response may be extended pursuant to 37 C.F.R. 1.136. See 37 C.F.R. 1.750. A failure to respond to this letter will result in the application papers being placed into the patent file with no further action taken on the application for patent term extension.

A determination has been made that U.S. Patent No. 6,068,832 is **NOT** eligible for patent term extension under 35 U.S.C. § 156 based upon the regulatory review period of DULERA®.

FDA official records indicate that each of the active ingredients comprising DULERA® were previously approved for commercial marketing or use prior to the approval of DULERA®. In the FDA letter, FDA stated:

> A review of the Food and Drug Administration's official records indicates that this product was subject to a regulatory review period before its commercial marketing or use, as required under 35 U.S.C. § 156(a)(4). However, our records also indicate that DULERA (mometasone furoate and formoterol fumarate) does not represent the first permitted commercial marketing or use of the product, as defined under 35 U.S.C. § 156(f)(1).
>
> The active ingredients in DULERA (mometasone furoate and formoterol fumarate) have been individually approved previously for commercial marketing

or use in several other approved products including, but not limited to the following:

Active Ingredient	Companies	Products	Application Numbers
Mometasone Furoate	Schering	Elocon topical Cream	NDA 19-625
"	Schering	Asmanex Twisthaler	NDA 21-067
"	Multiple (Altana, G&W Labs, Glenmark Generics, Taro, Tolmar)	Mometasone furoate top ical	ANDAs 76-171, 77-447, 78-541, 76-679, 76-591
Formoterol Fumarate	Novartis	Foradil Certihaler	NDA 21-592
"	Novartis	Foradil	NDA 20-831
"	Dey Pharma	Perforomist	NDA 22-007

Under 35 U.S.C. § 156(a), a term of a patent which claims a product shall be extended if, *inter alia*, the product has been subject to a regulatory review period before its commercial marketing or use. In addition, under § 156(a)(5)(A):

> the permission for the commercial marketing or use of the product . . . is the first permitted commercial marketing or use of the product under the provision of law under which such regulatory review period occurred; (Emphasis added)

Thus, the determination of eligibility of U.S. Patent No. 6,068,832 turns on the provisions in § 156(a)(5)(A) that the permission for the commercial marketing or use is the first permitted commercial marketing or use of the product. The term "product" is defined in 35 U.S.C. § 156(f) as follows:

> (f) For purposes of this section:
> (1) The term "product" means:
> (A) A drug product . . .
> (2) The term "drug product" means the active ingredient of -
> (A) A new drug, antibiotic drug, or human biological product . . . .including any salt or ester of the active ingredient, as a single entity or in combination with

another active ingredient. (Emphasis added.)

By the explicit terms of section 156(f)(2), the term "product" as it relates to a human drug product means the active ingredient of the new drug product. See In re Fisons Pharmaceuticals Limited, 231 USPQ 305 (Comm'r Pats. 1986); aff'd, Fisons plc v. Quigg, 8 USPQ2d 1491 (DDC 1988); aff'd, 10 USPQ2d 1869 (Fed. Cir. 1988) (holding that the term "product" as used in § 156(f) refers to the active ingredient); and Glaxo Operations UK Ltd. v. Quigg, 13 USPQ 1628 (Fed. Cir. 1990) (holding that the term "product" as used in § 156(f) refers to the active ingredient).

In addressing compliance with section 156 (a)(5)(A) for a drug product including two active ingredients, the court in Arnold P'ship v. Dudas, 362 F.3d 1338, 1341 (Fed. Cir. 2004) held that a composition comprised of multiple active ingredients is eligible for patent term extension only if at least one of the active ingredients complies with the first commercial marketing requirement of § 156(a)(5)(A). Thus, for regulatory review of a drug product with more than one active ingredient to give rise to eligibility for extension of a patent claiming the drug product, permission to commercially market and use the product must be the first permitted commercial marketing or use of at least one of the active ingredients. The active ingredients in the approved product DULERA® are mometasone furoate and formoterol fumarate. As noted in the FDA letter, the active ingredients of DULERA® had each been approved for commercial marketing and use prior to the approval of DULERA®. Furthermore, the prior approval of each of the active ingredients, mometasone furoate and formoterol fumarate, by the FDA occurred under section 505 of the FFDCA, the same provision of law under which regulatory review of the product DULERA® occurred. Thus, since neither of the active ingredients, mometasone furoate or formoterol fumarate, constitute the first permitted commercial marketing or use, the '832 patent does not appear to be eligible for extension based on the regulatory review of DULERA®.

Applying the definition of "product" provided in § 156(f) to the extension requirement of § 156(a)(5)(A), Applicant's product DULERA® does not qualify as the first permitted marketing or use of either active ingredient. Since the approval of DULERA® was not the first permitted marketing or use of at least one of the active ingredients thereof, mometasone furoate and formoterol fumarate, the patent is not eligible for patent term extension based upon the regulatory review of DULERA®.

Because the approval of DULERA® fails to comply with the requirement of section 156(a)(5)(A), the application for patent term extension of the '832 patent under 35 U.S.C. 156(d)(1) is **dismissed**

Any correspondence with respect to this matter should be addressed as follows:

By mail: Mail Stop Hatch-Waxman PTE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450.

By FAX: (571) 273-7755

Telephone inquiries related to this determination should be directed to the undersigned at (571) 272-7755.

Mary C. Tim
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Associate Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 51, Rm 6222
Silver Spring, MD 20993-0002

Attention: Beverly Friedman

RE: DULERA® (mometasone furoate and formoterol fumarate)
Docket No.: FDA-2011-E-142